IFW

AF/1623

PATENT
Customer No. 22,852
Attorney Docket No. 2405.0167

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Mads Liendgaard Vigh et al.	)	Group Art Unit: 1623
	)	
Application No.: 09/255,655	)	Examiner: H. Owens, Jr.
	)	
Filed: February 23, 1999	)	
	)	
For: USE OF D-TAGATOSE AS A PREBIOTIC FOOD COMPONENT	)	Confirmation No.: 8849
	)	

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL OF APPEAL BRIEF (37 C.F.R. 1.192)

Transmitted herewith in triplicate is the APPEAL BRIEF in this application with respect to the Notice of Appeal filed on November 25, 2003.

This application is on behalf of

☐ Small Entity ☒ Large Entity

Pursuant to 37 C.F.R. 1.17(c), the fee for filing the Appeal Brief is:

☐ $165.00 (Small Entity)

☐ $330.00 (Large Entity)

TOTAL FEE DUE:

Appeal Brief	$
Extension Fee (if any)	$1,480.00
Total Fee Due	$1,480.00

☒ Enclosed is a check for $1,480.00 to cover the above fees.

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this Appeal Brief, and such extension has not otherwise been requested, such an extension is hereby requested, and the Commissioner is authorized to charge necessary fees for such an extension to our Deposit Account No. 06-0916. A duplicate copy of this paper is enclosed for use in charging the deposit account.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 17, 2004

By: Charles E Van Horn
Charles E. Van Horn
Reg. No. 40,266

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MAY 17 2004
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PATENT
Customer No. 22,852
Attorney Docket No. 2405.0167

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

In accordance with 37 C.F.R. § 1.192, Appellants submit this Appeal Brief in triplicate without fee, accompanied by a four-month extension of time and a fee of $1,480.00. An Appeal Brief fee was paid January 7, 2002. The Board did not render a decision because prosecution was reopened by the Examiner on December 13, 2002. Accordingly, no Appeal Brief fee is required and submission of the Appeal Brief on or before May 26, 2004, is timely.

I. Real Party In Interest

The real party in interest in this application is the record owner, Arla Foods AMBA. The assignment was recorded on August 22, 2001 at Reel 12093, starting at Frame 0434.

II. Related Appeals and Interferences

None.

III. Status Of Claims

Claims 13-22 are pending in this application. Claims 1-12 have been canceled. Claims 13-22 stand rejected under 35 U.S.C. § 102(b).

IV. Status Of Amendments

No Amendment was filed subsequent to the date of the Final Office Action (August 27, 2003).

V. Summary Of Invention

The claimed invention is directed to either a method for selectively inducing production of butyrate by bacteria in a human colon (claims 13-17) or a method for selectively stimulating growth of lactobacilli and lactic acid bacteria in the human colon (claims 18-22). See Specification at page 6, line 34 to page 7, line 7. The methods include the step of administering D-tagatose, a well-known keto-hexose, in a daily amount of 5-30 grams to either selectively induce production of butyrate (claims 13-17; Figure 3; page 7, lines 28-33 and page 12, lines 1-6 of the Specification) or selectively stimulate the growth of lactobacilli and lactic bacteria in the human colon (claims 18-22; Figure 5; page 7, lines 28-33 and page 16, lines 6-11 of the Specification).

VI. Issues

Whether claims 13-22 are anticipated under 35 U.S.C. § 102(b) by the teachings of Zehner et al. (U.S. Patent No. 5,447,917).

VII. Grouping Of Claims

For purposes of this appeal, claims 13-22 stand or fall together. When a patent is granted, however, each claim will be entitled to a presumption of validity. 35 U.S.C. § 282.

VIII. Argument

A. Rejection

Claims 13-27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zehner (Zehner) (U.S. Patent No. 5,447,917). According to the Examiner, Zehner anticipates the claims because it teaches (columns 2-4, claims 1-3 – the entire patent except for the background) the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight, which encompasses the claimed daily administration of 5 to 30 grams. **As will be emphasized below, Zehner's only teaching of a dose is contained in claim 2 directed to a method of treating diabetes, and it is not described as a daily dose.** While the Examiner acknowledges that Zehner does not explicitly teach that D-tagatose is effective to "selectively" induce butyrate production or to "selectively" stimulate the growth of lactobacilli, in the human colon, it is the position of the Examiner that these effects are inherently achieved in Zehner via the administration of D-tagatose within the same dosage range for the treatment of hyperglycemia, diabetes and the inhibition of glycosylation end products. The Examiner has relied on *Ex Parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Int. 1993) for the legal principle that a claimed method of administering a known compound to a subject to achieve an effect not stated in the prior art is anticipated when the differently claimed effect is an inherent feature of the known compound previously administered to the same subject in the prior art.

The Examiner has further argued that the teachings of Zehner are not limited to a diabetic population and the population/subject as claimed are open to any human wherein D-tagatose is administered within the claimed dosage range. Zehner does teach that D-tagatose has a blood glucose lowering or anti-hyperglycemic effect when ingested that makes it effective as an anti-hyperglycemic agent (column 2, lines 14-20). Furthermore, Zehner teaches that the ingestion of D-tagatose results in the reduced formation of advanced glycosylated end products (column 2, lines 22-24; column 4, lines 30-33). Zehner further teaches that D-tagatose may be used to avoid an increase in blood glucose, treat hyperglycemia, treat diabetes mellitus, and to lower blood insulin in humans (column 3, lines 12-21). **As will be emphasized below, the only teaching in Zehner regarding a dosage for any of these treatments is contained in claim 2 which is limited to a method for treating diabetes.**

B. General Principles

Anticipation requires identity of the claimed process and a process of the prior art. The claimed process, including each step thereof, must have been described or embodied, either expressly or inherently, in a single reference. *Glaverbel Societe Anonyme v. Northlake Marketing & Supply Inc.*, 45 F.3d 1550, 1554, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). To support anticipation, the reference must be sufficiently clear so as to prove the existence of each and every element in the claim. *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

The reference may anticipate a claim if a missing element is inherent in the disclosure. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed.

Cir. 1999). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Id.*

C. Limitations Not Described

Zehner does not anticipate claims 13-22 because this reference fails to describe, either explicitly or inherently, a method for administering D-tagatose (1) to a human in need of either selective production of butyrate or selective stimulation of the growth of lactobacilli in the colon; (2) to a human in a daily amount of 5-30 grams (recited in claims 13 and 18) or a daily amount of 5-15 grams (recited in claims 15 and 20); or (3) to a human that would result in selectively inducing production of butyrate and selectively stimulating growth of lactobacilli and lactic acid bacteria in the colon. As will be explained in more detail below, each of these claim limitations patentably distinguish the claimed invention from the teachings of Zehner.

While Zehner does teach the administration of D-tagatose to a human to obtain a variety of effects, the only treatment associated with any suggested dosage in the Zehner patent is for treating diabetes (claims 1 and 2). The claims on appeal recite a method for treating a human in need of selective production of butyrate or selective stimulation of the growth of lactobacilli and lactic acid bacteria – a population of individuals different from the diabetics treated in the only method taught by Zehner associated with a suggested dosage of 1 gram per kilogram of weight of the mammal. Contrary to the position of the Examiner, the "subjects" of treatment are <u>not</u> identical in

Zehner and the claimed processes. The teachings of Zehner are silent on a suggested dosage of D-tagatose for the treatment of conditions or achieving certain effects other than the treatment of diabetes.

Secondly, the Examiner has taken the position that the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight encompasses the claimed daily administration of 5 to 30 grams. This position is not supported by the teachings of Zehner for at least the following reasons. First, the only teaching of a suggested dosage in Zehner appears in claim 2 of that patent. There is no indication in that claim, or any claim, or anywhere in the disclosure of the Zehner patent that the suggested dosage is a daily dosage. The written description in the Zehner patent is silent on a suggested dosage, the only examples are directed to tests conducted in rats, and the limitation in claim 2 (even considered in conjunction with claim 1) fails to describe a basis for the suggested dosage – every hour, every 12 hours, daily, every two days, weekly? Accordingly, it is respectfully submitted that Zehner does not contain a clear teaching of a dosage that encompasses or is encompassed by the claimed daily amount of 5-30 grams.

In addition to the total absence of any clear, specific dosage suggestion in Zehner, the claimed invention involves administration of D-tagatose in a daily amount of 5-30 grams that is significantly less than the dosage suggested in Zehner (1 g/kg of weight of the mammal) even if, arguendo, it could be interpreted as a daily dosage amount. For a diabetes patient to receive 30 grams according to the method of Zehner, they could weigh only 30 kg (about 81 pounds). There is no indication that Zehner is treating children or others with a relatively low body weight compared to a normal adult.

A diabetic patient weighing 160 pounds, if given a daily dosage in an amount recited in claim 2 of Zehner, would have to take almost twice the maximum daily amount specified in the claimed method. As noted at page 18, lines 23-28, oral intake of D-tagatose in excess of 30 grams per day is not suggested to avoid gastrointestinal side effects. Accordingly, the recited daily dosage of 5-30 grams is neither described nor suggested in the teachings of Zehner, either explicitly or inherently, for the treatment of any condition.

Finally, the Examiner has acknowledged that Zehner fails to explicitly describe that the administration of D-tagatose according to the claimed invention can be used to selectively induce production of butyrate by bacteria in the colon or to selectively stimulate the growth of lactobacilli and lactic acid bacteria in the colon. Rather, the Examiner has relied on the principle of inherency to anticipate the limitations in the claims on appeal. However, as noted and argued above, since the Examiner has failed to establish that Zehner teaches a method of administering D-tagatose to a population of individuals in an amount recited in each of the claims on appeal, these limitations cannot be inherently anticipated. While it may be possible that the selection of an appropriate individual, with an appropriate weight, in an appropriate dosage of D-tagatose may, by accident, meet at least some of the limitations of the claimed invention, inherency cannot be established by mere possibilities or even probabilities.

For the reasons discussed above, the Examiner has failed to establish that Zehner describes each and every limitation of the claimed invention either explicitly or inherently. The Board is respectfully requested to reverse the rejection of claims 13-22 under 35 U.S.C. § 102(b) to put this application in condition for allowance.

Appendix

An appendix is attached containing a copy of claims 13-22 involved in this appeal.

Please grant any extensions of time required to enter this Appeal Brief and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 17, 2004

By: Charles E Van Horn

Charles E. Van Horn
Reg. No. 40,266

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Customer No. 22,852

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APPENDIX TO APPLICATION NO. 09/255,655

13. A method for selectively inducing production of butyrate by bacteria in the colon of a human in need thereof comprising administering D-tagatose to said human in a daily amount of 5-30 grams to selectively induce production of butyrate.

14. A method according to claim 13 wherein D-tagatose is administered orally.

15. A method according to claim 13 wherein the daily amount is 5-15 grams.

16. A method according to claim 14 wherein D-tagatose is administered orally in a food product.

17. A method according to claim 16 wherein the food product is selected from a confectionery, chewing gum, ice cream, desert, soft drink, breakfast cereal, yogurt, health drink and health bar.

18. A method for selectively stimulating growth of lactobacilli and lactic acid bacteria in the colon of a human in need thereof comprising administering D-tagatose to a human in a daily amount of 5-30 grams to selectively stimulate growth of lactobacilli and lactic bacteria in the colon.

19. A method according to claim 18 wherein D-tagatose is administered orally.

20. A method according to claim 18 wherein the daily amount is 5-15 grams.

21. A method according to claim 19 wherein D-tagatose is administered orally in a food product.

22. A method according to claim 21 wherein the food product is selected from a confectionery, chewing gum, ice cream, dessert, soft drink, breakfast cereal, yogurt, health drink and health bar.